
INSTRUCTIONS

SAMPLE COLLECTION, PREPARATION AND SHIPMENT

INTRODUCTION

This manual contains information and step-by-step procedures for preparing and shipping samples to ViroMed to be tested under the Navy HIV Testing Contract (N00140-03-D-N800).

INTENDED USERS

This manual is intended for any personnel responsible for drawing, labeling, packing and shipping specimens to be tested under the Navy HIV Testing Contract.

BEFORE YOU BEGIN

Read this manual in its entirety before proceeding.

Assemble all supplies required before you begin so that you are aware of any missing components. [See page 2-3 for a complete listing of all supplies provided under this contract.]

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For questions, please contact ViroMed Client Services at 800.582.0077

Supplies Provided By ViroMed

- Supplies will be shipped to the SAs on a quarterly basis.
- Requests for supplemental supply shipments should be directed to ViroMed Client Services at 800-582-0077.

- **Primary Serum Separator Tubes (SST)** – 7ml, plastic, double-gel serum separator tubes. Brand name is Vacuette. To be used for all blood draws sent to ViroMed.



- **5ml screw top serum transfer tubes** – 5ml, white, plastic, round-bottom screw top transfer tube. To be used to pour off serum if unable to draw or send blood samples in the Vacuette tubes.



- **Foam tube holders** – Dimensions = 9 1/2" x 3 3/4" x 3 15/16". 1 1/2# foam block drilled with 40 slots to hold both the SSTs and the 5ml screw top transfer tubes.



- **Ziplock bags** – Clear, plastic bag with a ziplock closure. Dimensions = 15 1/2" x 12". Each ziplock bag will hold one tube holder.

[Ziplock bags not pictured]

- **Small shipping box** – Dimensions = 10 1/8" x 8 5/8" x 5". Printed with an "up" arrow on both sides. This box will hold two foam tube holders.

[Small shipping box not pictured]

- **Medium shipping box** – Dimensions = 19 5/8" x 8 5/8" x 5". Printed with an "up" arrow on both sides. This box will hold four foam tube holders.

[Medium shipping box not pictured]

- **OCONUS shipping system** – OCONUS shipping box, insulation and refrigerant packs.

- Shipping box – Dimensions = 23 1/8" x 12 1/8" x 5 5/8". Printed with an arrow on both sides. This box is to be used in conjunction with the foam insulation and refrigerant packs. It will hold a maximum of four foam tube holders.

- Insulation – A complete set consists of six pieces of white foam insulation to be placed inside the OCONUS shipping box.

- Refrigerant Packs – Reusable Polar Packs to be frozen at the OCONUS sites and used with the OCONUS shipping box and the foam insulation.



- **Tamper-proof stickers** – Serial-numbered stickers to be applied to the closure of each ziplock bag containing samples. When using a tamper-proof sticker, you must initial and date it before you place the sticker on the ziplock.



- **Shipping tape** – Each roll of shipping tape can be used with the dispenser.



- **Pre-printed barcode labels** – Self-adhesive labels coded with a unique 10-digit barcode number. See Page 6 for specific instructions on placing these labels on sample tubes.



- **Pre-printed airbills** – FedEx airbills pre-printed with your site address. One airbill should be used for each box sent to ViroMed.

Examples of airbills are located on pages 9, 10, 14 and 15 of this section

- **CDC Permit** – Biomedical Materials, Etiological Agents or Vectors (OCONUS). A copy of the CDC permit must be placed on all packages being sent to ViroMed from OCONUS sites.



- **Saturday delivery stickers** – FedEx Saturday delivery stickers should be placed on any boxes being shipped to ViroMed on a Friday (CONUS sites). These stickers work in conjunction with the pre-printed airbills that are already marked for Saturday delivery.



- **Infectious shipping containers** - Used to ship known infectious substances to ViroMed. IATA compliant.



Sample Collection

- Collect blood samples using the 7ml, plastic, double-gel serum separator tubes (SSTs) provided by ViroMed. Submit blood samples to ViroMed in the SST.
- Using a vacutainer-type needle system, draw blood samples into the SST until the tube is full.



- Allow samples to sit at room temperature for up to 30 minutes. ***Do not refrigerate tubes prior to centrifugation.***
- Once the samples have clotted, centrifuge tube immediately at 1100 – 1300 g for a minimum of 10 minutes and maximum of 2 hours to complete serum separation.
- Samples may be stored in the SST at 2 - 8°C for up to seven (7) days.
- Samples that will not arrive at ViroMed within seven (7) days from the date drawn must be poured off and frozen until transshipment. Transfer the serum to the 5ml screw cap serum transfer tubes provided by ViroMed and freeze at -20°C or colder.
- If unable to collect blood samples in the SST provided by ViroMed, submit serum samples to ViroMed by pouring off into the 5ml screw cap transfer tube provided by ViroMed. ***Do not inject serum into the SSTs.***



- Do not submit samples in any tube other than those provided by ViroMed. Samples submitted in tubes other than the 7ml SST or the 5ml screw cap transfer tube will be rejected. Examples of unacceptable tube types are:
 - Glass tubes of any kind
 - Serum transfer tubes with flat bottoms
 - Serum transfer tubes larger than 5ml (21mm x 75mm)
 - Serum transfer tubes with snap caps rather than screw caps

Sample Rejection Issues

Samples found to be unacceptable for testing will be rejected at ViroMed using the deficiency codes indicated below.

Deficiency Code	Description	Action
D-1	No Record Received	Hold
D-2	No Specimen Received	Hold
D-3	Deficiency (Duplicate Barcode)	Hold
D-4	Other Problem (invalid submission/date drawn.	Reject/Resubmit Sample
D-5	Data Mismatch	Reject/Resubmit Sample
D-6	No Specimen Barcode	Reject/Resubmit Sample
D-7	Grossly Hemolyzed	Reject/Resubmit Sample
D-8	Quantity Not Sufficient	Reject/Resubmit Sample
D-9	Individual Specimen Contamination or Gross Leakage	Reject/Resubmit Sample

- Samples that are rejected using codes D-4 through D-9 will NOT be tested. The sample MUST be resubmitted.
- Samples whose barcode labels are not correctly attached to the SST tube (see Page 6 for details) or have barcodes that cannot be scanned will be rejected as D-4. During the routine testing process, samples are diluted using automated equipment. If the dilutor cannot scan the barcode label, the tube cannot continue through the testing process. Quality standards prevent ViroMed staff from typing in barcode numbers by hand.
- Samples that leak in transit will contaminate other samples contained within that ziplock bag. The possibility that the leaked sample may contain any bloodborne pathogen prevents us from:
 - Opening the package and putting our laboratory personnel at risk for exposure.
 - Testing samples that have even a remote possibility of being contaminated.
- ViroMed understands that it is not always easy (and in some cases impossible) to recollect samples. Therefore, you must carefully examine all samples collected so that you can immediately correct a submission format error or redraw an inappropriate sample. If you have questions as to the quality of a sample or the specific ViroMed rejection criteria CALL VIROMED. We can work together to avoid major problems!

Labeling Sample Tubes

DO Place Label Starting at the Top of the Tube

- **All barcode labels must be** applied starting at the top of the sample tube (the end closest to the cap). The barcode must be placed on the tube in a vertical position.



Never Place Labels at the Bottom of the Tube

- **No labels of any kind** can be placed on the bottom portion of the sample tube. Samples received with labels covering the bottom half inch of the samples tube will be rejected.



Never Place Labels Horizontally on the Tube

- **Barcode labels must be** placed vertically. Barcodes placed on tubes horizontally will be rejected.



No Wrinkles, Folds or Tears in Labels

- **Barcode labels must be** placed on the tube so that there are no wrinkles, folds or tears on the barcode itself. Samples received with damaged barcodes will be rejected.



No Incomplete or Illegible Labels

- **Barcode labels must be** complete and legible and have no blanks or smudges. Samples with barcodes that cannot be read by the barcode scanner will be rejected.



Packaging Instructions

- Place centrifuged, barcoded SSTs or 5ml screw cap serum transport tubes upright in the foam tube holder.
- Place the filled tube holder into a ziplock bag (provided by ViroMed). Release all air from the ziplock and seal the bag.
- With the tubes sitting upright on a flat surface, fold the two top corners of the bag in toward the middle. Then (with the corners tucked in) fold the top of the bag over until it is flush with the tube holder.
- Initial and Date the tamper proof sticker. Place the ViroMed-provided tamper proof sticker across the entire folded end of the bag, wrapping excess label around to the sides.

NOTE: The tamper proof sticker must cover and seal the entire bag opening.



- Place the sealed tube holder into the shipping box.
 - Two tube holders fit into the small box.
 - Four tube holders fit into the medium box and OCONUS box.
 - If you are shipping a box that is not completely full, you must fill the empty space with either an empty tube holder or other suitable materials (i.e., crumpled newspaper – please *do not* use shredded paper or Styrofoam peanuts).
- Tape the box shut and place a FedEx airbill on the top of the outside of the box. [See page 9 for instructions on completing this airbill.]

NOTE: Each individual box must have its own completed airbill. Do not utilize the same airbill for more than one box. It is unacceptable to tape boxes together for shipment.

Special Handling for OCONUS Sites

- After the shipping box has been assembled, place the foam insulation into place. Each insulation set consists of 6 pieces.
- Place the sealed tube holder(s) into the OCONUS shipping box. Four tube holders will fit into a box.
- Place one foam refrigerant pack along each short side of the box and one in the middle of each long side.
- If you are shipping a box that is not completely full, you must fill the empty space with either an empty tube holder or other suitable material (i.e., crumpled newspaper).
- After the box has been filled, place the last piece of foam on top of the tube holders and seal the box. Place the FedEx International Air Waybill and a CDC Permit (Biomedical Materials, Etiological Agents or Vectors) on the top of the outside of the box. [See Page 10 for instructions on completing the airbill.]



NOTE: Each individual box must have its own completed airbill. Do not utilize the same airbill for more than one box. It is unacceptable to tape boxes together for shipment.

Filling out the FedEx USA Airbill

- Pre-printed FedEx USA Airbills are provided to all CONUS sites. The following sections have been completed for the sender:
 - Sender address
 - Receiver address
 - Express Package Service
 - Packaging
 - Special Handling
 - Payment – The airbills are marked for Receiver Billing with ViroMed’s account number.

- The **sender must complete** the following fields on the pre-printed FedEx Airbill:
 - Section 1: Date
 - Section 1: Sender’s Name
 - Section 7: Total Packages
 - Section 7: Total Weight

NOTE: Do NOT sign the airbill.

Filling out the FedEx International Air Waybill

- Pre-printed FedEx International Air Waybills are provided to all OCONUS sites. The following sections have been completed for the sender:
 - Sender address
 - Receiver address
 - Service
 - Packaging
 - Special Handling
 - Payment – The air waybills are marked for Receiver Billing (for both the transportation charges and the duties and taxes), with ViroMed's account number.

The image shows a FedEx International Air Waybill form. Red arrows point to the following sections:

- Section 1: Sender's Name and Address (Top left)
- Section 4: Total Packages and Weight (Bottom left)
- Section 10: Sender's Signature and Date (Bottom right)
- Sender's Copy (Right side, top)
- Receiver's Copy (Right side, bottom)

- The **sender must complete** the following fields on the pre-printed FedEx International Air Waybill:
 - Section 1: Date
 - Section 1: Sender's Name
 - Section 4: Total Packages
 - Section 4: Total Weight
 - Section 10: Sender's Signature and Date

Arranging for A FedEx Pick-Up

- Call FedEx at 1.800.463.3339 (1.800.GO.FEDEX).
- Press '0' to talk to a Customer Service Agent and request a shipment pick-up.
- Have the following information ready when you place the call:
 - Facility name, address and phone number
 - Number of packages and approximate weight
 - What time the package(s) will be ready
 - How late your facility will be open for the pick-up
- It is recommended that submitting activities establish a scheduled pick-up with FedEx if they have routine or daily pick-ups.

ORDERING ADDITIONAL PRE-PRINTED AIRBILLS

- Call ViroMed Client Services at 1.800.582.0077.
- Tell the Client Service Representative that you need to order additional pre-printed airbills under the Navy HIV Testing Contract.
- Provide the Representative with the following information:
 - Site Identification Code from the "Company" line of your airbill
 - Site name and address
 - Quantity needed
- Your supply of pre-printed airbills will be delivered within 7-10 working days.

Packaging Infectious Substances

- Verify that you have all required components of the infectious substances shipping container.
- Place the plastic divider inside the vessel.
- For instructions on sample collection and labeling, see Pages 4 – 6.
- Roll each tube into an individual sheet of bubble wrap.
- Slide the bubble wrapped tube into one section of the vessel and screw on the lid.
- Slide the vessel into the outer box and close the flaps in the order indicated by the numbers on the flap. Secure with tape.
- Be sure that the "Shipper" and "Consignee" sections on the outside of the box are completed carefully and entirely with correct addresses and phone numbers. FedEx will refuse any packaging with incomplete information.
- Place the pre-printed airbill and pre-printed shippers declaration for dangerous goods on the top of the box. [See Page 13 or 15 for instructions on filling out this airbill.]



Filling out the FedEx Airbill for Dangerous Goods

- Dangerous goods shipments require a Shippers Declaration form in addition to the pre-printed airbill.

Pre-Printed Airbill

- The **sender must complete** the following fields on the **pre-printed airbill**:
 - Section 1: Date
 - Section 1: Sender's Name
 - Section 6: Check the "YES, (As per Attached Shippers Declaration)" box
 - Section 7: Total Packages
 - Section 7: Total Weight

NOTE: Do NOT sign the airbill.

FedEx. USA Airbill 836477134315 0200 **Sender's Copy**

1 From (please print and press hard)
Date: _____ Sender's FedEx Account Number: _____
Sender's Name: **YOUR NAME** Phone: **(000) 000-0000**
Company: **YOUR COMPANY**
Address: **YOUR ADDRESS**
City: **YOUR CITY** State: **PA** ZIP: **55343**

2 To (please print and press hard)
Recipient Name: **Attn: Government Lab** Phone: **(952) 931-0077**
Company: **Vivimed Laboratories Inc.**
Address: **14-A-11 4700 Park Glen Road**
City: **St. Louis Park** State: **MN** ZIP: **55416**

3 Service Selection
4a Express Package Service Packages under 100 lbs.
☐ FedEx Priority Overnight ☐ FedEx Standard Overnight
☐ FedEx First Overnight ☐ FedEx 2Day
☐ FedEx Overnight Freight ☐ FedEx 2Day Freight ☐ FedEx Express Saver Freight

4b Express Freight Service Packages over 100 lbs.
☐ FedEx Overnight Freight ☐ FedEx 2Day Freight ☐ FedEx Express Saver Freight

5 Packaging ☐ FedEx ☐ Other

6 Special Handling
Does this shipment contain dangerous goods? ☐ Yes ☐ No

7 Payment
☐ Prepaid ☐ Collect ☐ Other

8 Signature
Sender's Signature: _____

Total Packages: _____ **Total Weight:** _____ **Total Declared Value:** _____ **Total Charges:** _____

321

Questions? Call 1-800-Go-FedEx 800-468-3338 **The World On Time.**

Continue to the next page for filling out the Fed Ex Airbill for Dangerous Goods

Filling out the FedEx Airbill for Dangerous Goods

- Dangerous goods shipments require a Shippers Declaration form in addition to the pre-printed airbill.

Shipper's Declaration for Dangerous Goods

- The *sender must complete* the following fields on the *pre-printed Shippers Declaration for Dangerous Goods*:
 - Write the airbill number in the upper right hand corner, using the airbill from the previous step.
 - Write the appropriate number of MLS on the provided line within the body of the declaration.
 - Write the following information in the space provided in the lower right hand corner of the form:
 - Name/Title of signatory (Please PRINT!)
 - Place (City/State) and Date (Please PRINT!)
 - Signature

SHIPPER'S DECLARATION FOR DANGEROUS GOODS (Provide at least two copies to the airline.)

Shipper: TEST
 YOUR COMPANY
 YOUR ADDRESS
 YOUR CITY, STATE, ZIP CODE
 YOUR PHONE #

Air Waybill No. _____
 Page _____ of _____ Pages
 Shipper's Reference Number (optional) _____

Consignee:
 VIROMED LABORATORIES, INC.
 (HALL) 4700 PARK BLVD ROAD
 ST. LOUIS PARK, MN 55416
 (952) 563-3300

Two completed and signed copies of this Declaration must be handed to the operator.

TRANSPORT DETAILS
 This shipment is within the limitations prescribed for:
 (delete non applicable)
☐ PASSENGER AND CARGO AIRCRAFT ☒ CARGO AIRCRAFT ONLY

Airport of Departure: _____
 Airport of Destination: MPLS / ST. PAUL

WARNING
 Failure to comply with all respects with the applicable Dangerous Goods Regulations may be in breach of the applicable law, subject to legal penalties. This Declaration must not, in any circumstances, be completed and/or signed by a consolidator, a forwarder or an IATA cargo agent.

Shipment type: (delete non applicable)
☒ NON-RADIOACTIVE ☐ RADIOACTIVE

NATURE AND QUANTITY OF DANGEROUS GOODS
 Proper Shipping name, Class or Division, UN Number or Identification Number, Packing Group (if required), and all other required information

INFECTIOUS SUBSTANCE, 6.2 UN 2814 1 FIBERGLASS BOX 602 CONTAINING _____MLS
 AFFECTING HUMANS.
 (HUMAN IMMUNODEFICIENCY VIRUS)

Additional Handling Information
 PRIOR ARRANGEMENTS AS REQUIRED BY THE ICAO/IATA DANGEROUS GOODS REGULATIONS 1.3.3.1, HAVE BEEN MADE.
 Emergency Telephone Number (800) 451-8346

CHECK ONE:
☒ ICAO/IATA ☐ 49 CFR

I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name, and are classified, packaged, marked and labelled/placarded, and are in respect to proper condition for transport according to applicable International and National Governmental Regulations.

Emergency Telephone Number (Required for US Origin or Destination Shipments) _____

Name/Title of Signatory _____
 Place and Date _____
 Signature (see warning above) _____

IF ACCEPTABLE FOR PASSENGER AIRCRAFT, THIS SHIPMENT CONTAINS RADIOACTIVE MATERIAL INTENDED FOR USE IN, OR INCIDENT TO, RESEARCH, MEDICAL DIAGNOSIS, OR TREATMENT.

FedEx M-1421C 10/98 LOGO# 146491

NOTE: You MUST follow explicitly all packaging and labeling instructions for shipping infectious substances. Correct spelling and legibility are important. Otherwise, your package will be delayed or may be rejected by FedEx.

International Shipment of Infectious Substances

- Infectious substances (known positive samples) must be packed properly in the approved infectious shipper provided by ViroMed.
- The package must have a properly completed International Air Waybill and a separate Shipper's Declaration for Dangerous Goods.

Filling out the International Air Waybill

- The **sender must complete** the following fields on the pre-printed International Air Waybill:
 - Section 1: Date
 - Section 1: Sender's Name
 - Section 4: Total Packages
 - Section 4: Total Weight
 - Section 8: Check the "YES, (As per attached Shippers Declaration)" box
 - Section 10: Sign and Date the airbill

The image shows a FedEx International Air Waybill form. Red arrows point to the following sections:

- Section 1: Sender's Name and Address (Top left)
- Section 4: Packages and Weight (Bottom left)
- Section 8: Check for Dangerous Goods (Middle right)
- Section 10: Signature and Date (Bottom right)

The form is filled out with sample data, including 'VIRIDEX LABORATORIES, INC.' and 'STAGNOSTIC SPECIMENS'.

Continue to the next page for filling out the International Fed Ex Airbill for Dangerous Goods

International Shipment of Infectious Substances

- Infectious substances (known positive samples) must be packed properly in the approved infectious shipper provided by ViroMed.
- The package must have a properly completed International Air Waybill and a separate Shipper's Declaration for Dangerous Goods.

Filling out the Shippers Declaration for Dangerous Goods

- The **sender must complete** the following fields on the pre-printed Shippers Declaration for Dangerous Goods:
 - Write the airbill number in the upper right hand corner, using the airbill from the previous step.
 - Write the appropriate number of MLS on the provided line within the body of the declaration.
 - Write the following information in the space provided in the lower right hand corner of the form:
 - Name/Title of Signatory (Please PRINT!)
 - Place (City, State/Province, Country) and Date (Please PRINT!)
 - Signature

SHIPPER'S DECLARATION FOR DANGEROUS GOODS (Provide at least two copies to the airline.)

Shipper: TEST
YOUR COMPANY
YOUR ADDRESS
YOUR CITY, STATE, ZIP CODE
YOUR PHONE #

Air Waybill No. _____
Page _____ of _____ Pages
Shipper's Reference Number (optional) _____

Consignee:
VIROMED LABORATORIES, INC.
(HAL) 4700 PARK GLEN ROAD
ST. LOUIS PARK, MN 55416
(952) 563-3300

Two completed and signed copies of this Declaration must be handed to the operator

TRANSPORT DETAILS
This shipment is within the limitations prescribed for: (delete non applicable)
☐ PASSENGER AND CARGO AIRCRAFT ☒ CARGO AIRCRAFT ONLY
Airport of Departure: _____
Airport of Destination: MPLS / ST. PAUL

WARNING
Failure to comply with all respects with the applicable Dangerous Goods Regulations may be in breach of the applicable law, subject to legal penalties. This Declaration must not, in any circumstances, be completed and/or signed by a consolidator, a forwarder or an IATA cargo agent.

Shipment type: (delete non applicable)
☒ NON-RADIOACTIVE ☐ RADIOACTIVE

NATURE AND QUANTITY OF DANGEROUS GOODS
Proper Shipping name, Class or Division, UN Number or Identification Number, Packing Group (if required), and all other required information

INFECTIOUS SUBSTANCE, 6.2 UN 2814 1 FIBER OPTIC BOX 602 CONTAINING ____MLS

Additional Handling Information
PRIOR ARRANGEMENTS AS REQUIRED BY THE IATA, DANGEROUS GOODS REGULATIONS 4.3.3.1, HAVE BEEN MADE.
Emergency Telephone Number (800) 451-8346

I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name, and are classified, packaged, marked and labelled/placarded, and are in proper condition for transport according to applicable International and National Governmental Regulations.

Emergency Telephone Number (Required for US Origin or Destination Shipments) _____

Name/Title of Signatory _____
Place and Date _____
Signature (see warning above) _____

IF ACCEPTABLE FOR PASSENGER AIRCRAFT, THIS SHIPMENT CONTAINS RADIOACTIVE MATERIAL INTENDED FOR USE IN, OR INCIDENT TO, RESEARCH, MEDICAL DIAGNOSIS, OR TREATMENT.

FedEx 16-1427C 10/98 100029 148491

NOTE: You MUST follow explicitly all packaging and labeling instructions for shipping infectious substances. Correct spelling and legibility are important. Otherwise, your package will be delayed or may be rejected by FedEx.